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20350	7590	11/16/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP			SINES, BRIAN J	
TWO EMBARCADERO CENTER			ART UNIT	
EIGHTH FLOOR			PAPER NUMBER	
SAN FRANCISCO, CA 94111-3834			1743	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/998,600

Applicant(s)

UNGER ET AL.

Examiner

Brian J. Sines

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 61-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-31 and 33-60 is/are rejected.
- 7) ☒ Claim(s) 8 and 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I comprising claims 1 – 60 in the reply filed on 8/3/2004 is acknowledged.

Claims 61 – 66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

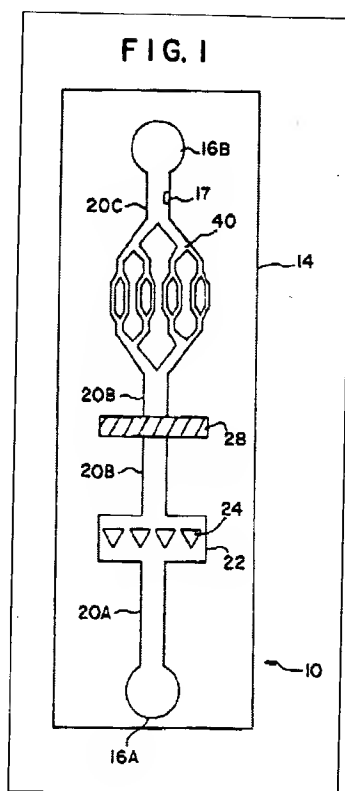
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

1. Claims 1, 2, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilding et al. (U.S. Pat. No. 5,304,487 A). Regarding claim 1, Wilding et al. teach a microfluidic device (10) comprising: a body structure comprising an elastomeric polymer substrate (14); a microfluidic channel (e.g., 20A & 20B) disposed within the substrate; a port (e.g., 16A) on a surface of the body structure and in fluid communication with the microfluidic channel for introducing a fluid to or from the microfluidic channel; and a means, such as a pump, for transporting the fluid to and from the microfluidic channel (see col. 6, lines 41 – 61; col. 9, lines 5 – 48; figure 1). Although Wilding et al. teach

that silicon is preferred, an elastomeric polymer, such as polytetrafluoroethylene, may also be used in the fabrication of the device (see col. 5, lines 55 – 62).

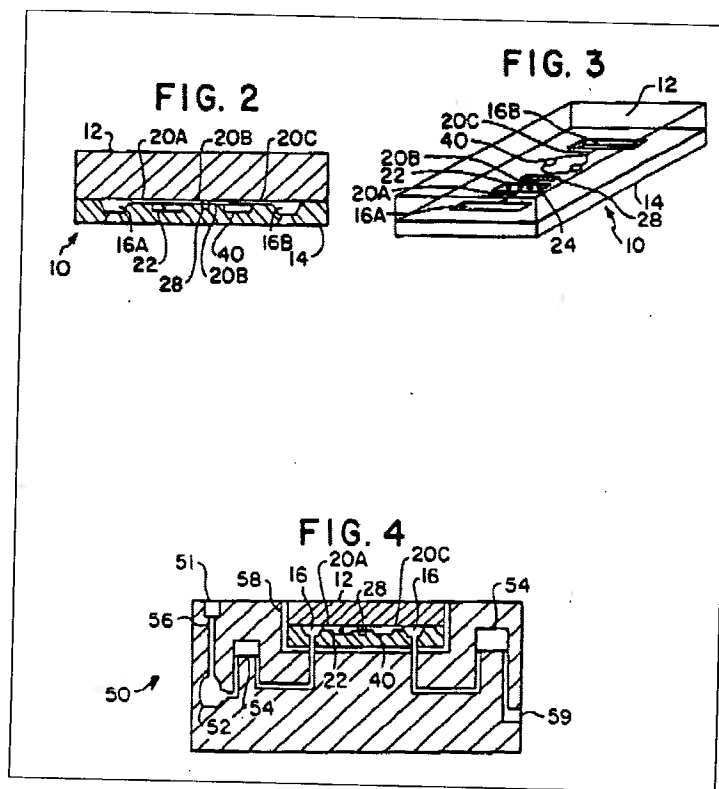


Regarding claim 2, Wilding et al. do teach the use of polytetrafluoroethylene (e.g., also known as Teflon) as a fabrication material for the device. The applicants specification also discloses that polytetrafluoroethylene may be used in fabricating the claimed device (see p. 20, lines 4 – 13). Since the materials taught by Wilding et al. are identical to those disclosed by the applicant, it is presumed that the material properties are identical as well. Regarding claims drawn to a product or apparatus statutory class of invention, when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent. In addition, if the prior art teaches the identical chemical structure or component, the properties applicant discloses and/or claims are necessarily present (see MPEP § 2112.01). Therefore, it is

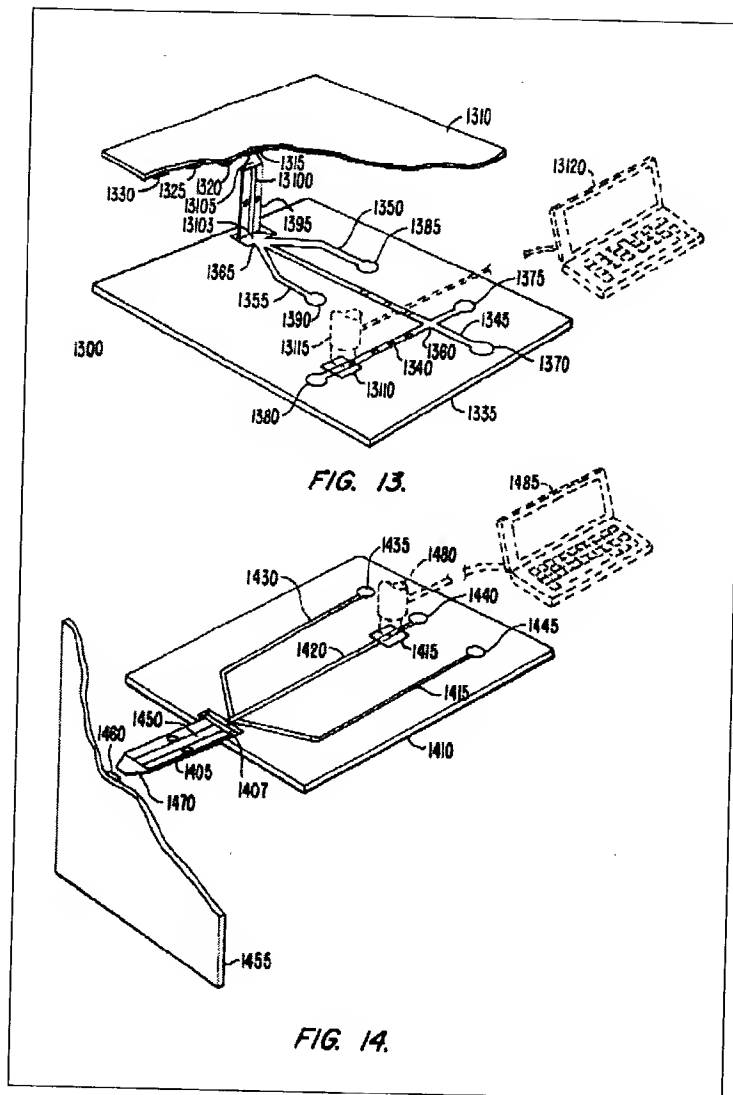
inherently anticipated that the substrate disclosed by Wilding et al. has a Young's modulus of about 3 MPa or less (see MPEP § 2112; see also MPEP § 2145, part II).

Regarding claim 24, Wilding et al. teach that the body structure comprises a plurality of ports (e.g., 16A & 16B) (see col. 9, lines 5 – 27; figure 1).

Regarding claim 25, Wilding et al. teach that the body structure (14) further comprises a passageway defining an interstitial surface and which extends from a first surface (e.g., the top of substrate 14) to a second surface (e.g., bottom of the surface of substrate 14) of the body structure, wherein the port (16A & 16B) is disposed within the interstitial surface (e.g., at the bottom outlet portion midpoint of substrate 14) (see figures 2 – 4).



2. Claims 1, 2, 7, 16, 18, 19 and 21 – 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Knapp et al. (U.S. Pat. No. 6,391,622 B1). Knapp et al. teach a microfluidic device comprising: a body structure comprising an elastomeric polymer substrate (1335 & 1410); a microfluidic channel (e.g., 1345 & 1415) disposed within the substrate; a port or well structure (e.g., 1370, 1445, 1470, 13105) on a surface of the body structure and in fluid communication with the microfluidic channel for introducing a fluid to or from the microfluidic channel; and a means, such as a micropump, for transporting the fluid to and from the microfluidic channel (see col. 41, lines 22 – 44; col. 55, line 21 – col. 56, line 53; figures 13 & 14). Knapp et al. do teach that a material transport system, such as a micropump and a valve system, is incorporated within the apparatus (see col. 10, lines 9 – 15).



Regarding claim 2, Knapp et al. do teach the use of preferred polymeric materials comprising, e.g., polydimethylsiloxane (PDMS) and polyurethane, as a fabrication material for the device. (see col. 41, lines 22 – 44). The applicants specification also discloses that the same polymeric materials may be used in fabricating the claimed device (see p. 18, line 3 – p. 20, line 13). Since the materials taught by Knapp et al. are identical to those disclosed by the applicant, it is presumed that the material properties are identical as well. Regarding claims drawn to a product or apparatus statutory class of invention, when the structure or composition recited in the reference is substantially

identical to that of the claims, claimed properties or functions are presumed to be inherent. In addition, if the prior art teaches the identical chemical structure or component, the properties applicant discloses and/or claims are necessarily present (see MPEP § 2112.01). Therefore, it is inherently anticipated that the substrate disclosed by Wilding et al. has a Young's modulus of about 3 MPa or less (see MPEP § 2112; see also MPEP § 2145, part II).

Regarding claim 16, Knapp et al. teach that the body structure further comprises an elongated capillary or electropipettor protruberance (e.g., 1405), wherein the port (e.g., 1470) is disposed on the tip of the elongated capillary protruberance (see col. 5, lines 7 – 36; col. 10, lines 16 – 21; col. 56, lines 6 – 37; figure 14).

Regarding claims 7 and 18, as shown in figure 14, Knapp et al. teach that the microfluidic channel (e.g., portion 1405) is tapered towards the port (e.g., portion 1470).

Regarding claims 19 and 22, Knapp et al. anticipate a port further comprising a capillary interface, such as a capillary element comprising a capillary channel disposed therethrough, wherein at least one end of the capillary element is inserted into the port and positioned such the capillary channel is in fluid communication with the microfluidic channel (see col. 5, lines 7 – 36; col. 10, lines 16 – 21; col. 56, lines 6 – 64; figures 13, 14 & 16).

Regarding claim 21, as shown in figure 14, Knapp et al. teach that the diameter of a port (e.g., 1435) is substantially greater than the diameter of the microfluidic channel (e.g., 1430) (see col. 56, lines 6 – 37).

Regarding claim 23, Knapp et al. anticipate that the capillary element (e.g., 1405) is removably attached to the elastomeric substrate (1410), since the capillary element can be a separate structure not integrated with the substrate (see figure 14).

Regarding claim 24, Knapp et al. teach that the body structure comprises a plurality of ports (e.g., 1370, 1375, 1380, 1385 & 1390) (see col. 55, lines 21 – 43; figure 13).

Claim Rejections - 35 USC § 103

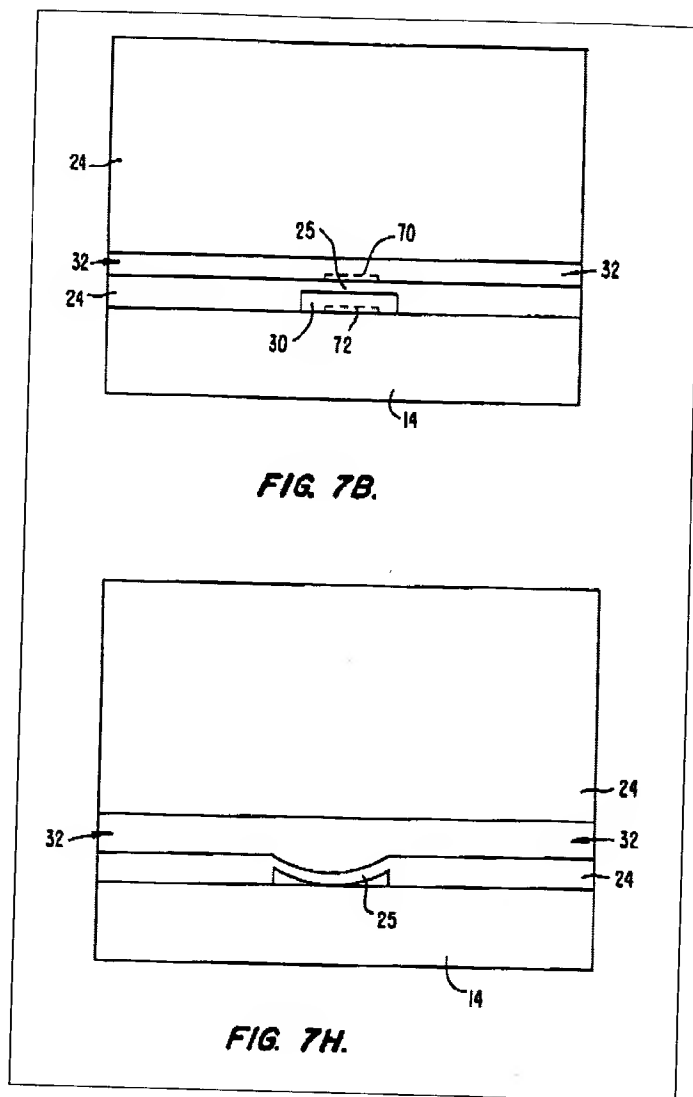
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
1. Claims 3 – 6, 9 – 15, 26 – 31 and 33 – 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knapp et al. in view of Unger et al. (U.S. Pat. No. 6,408,878 B2). Knapp et al. teach a microfluidic device comprising: a body structure comprising an elastomeric polymer substrate (1335 & 1410); a microfluidic channel (e.g., 1345 & 1415) disposed within the substrate; a fluid inlet, port or well structure (e.g., 1370, 1445, 1470, 13105) on a surface of the body structure and in fluid communication with the

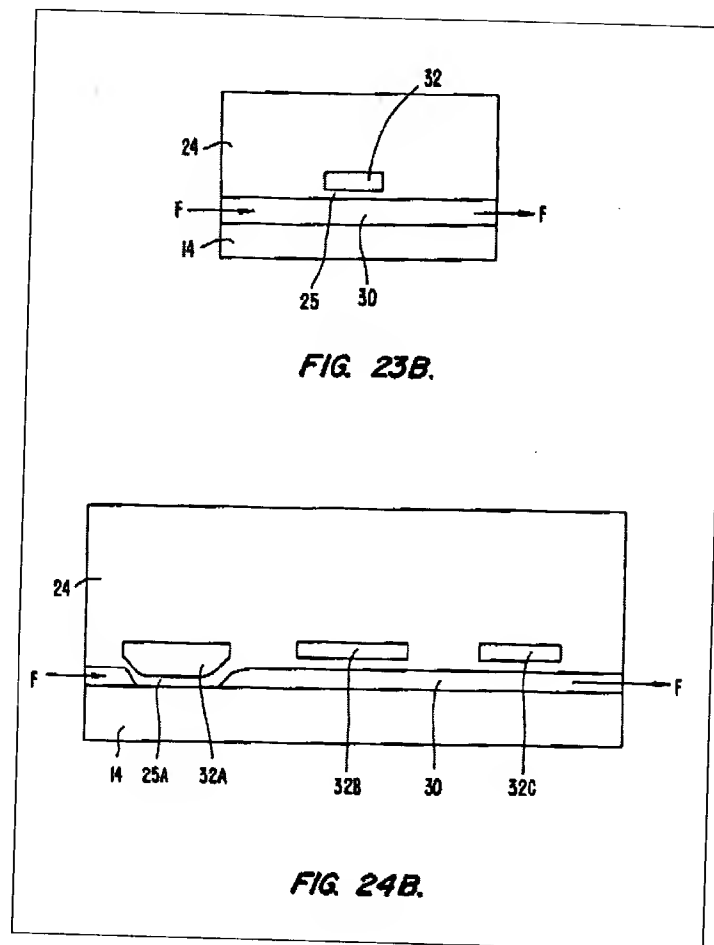
microfluidic channel for introducing a fluid to or from the microfluidic channel; and a means, such as a micropump, for transporting the fluid to and from the microfluidic channel (see col. 41, lines 22 – 44; col. 55, line 21 – col. 56, line 53; figures 13 & 14). Knapp et al. do teach that a material transport system, such as a micropump and a valve system, is incorporated within the apparatus (see col. 10, lines 9 – 15). Although Knapp et al. do teach that a material transport system, such as a micropump and a microvalve system, is incorporated within the apparatus, Knapp et al. is silent to the specific teaching of the elastomeric microfluidic valve system, as recited in claims 3, 29, 30 and 31 (see col. 5, lines 1 – 36; col. 10, lines 9 – 15). However, Unger et al. do teach an elastomeric microfluidic valve/pump system. Unger et al. teach an elastomeric valve system comprising: a control channel (32) and a microfluidic channel (30) disposed within an elastomeric polymer substrate (24); and a valve/pump structure (membrane 25) operatively connected to the microfluidic channel to regulate fluid flow through the microfluidic channel, wherein the valve (25) comprises a portion of the elastomeric polymer substrate that is located between the control channel and the microfluidic channel, wherein the valve is capable of being deflected into or retractable from the microfluidic channel upon which the valve operates in response to an actuation force applied to the valve, wherein the valve when positioned in the microfluidic channel is capable of affecting fluid flow therethrough (see col. 8, line 52 – col. 35, line 40; col. 39, line 43 – col. 41, line 25; figures 7B & 7H).



The elastomeric microfluidic valve system disclosed by Unger et al. is considered functionally equivalent to the microfluidic valve systems utilized in the device disclosed by Knapp et al. (see MPEP § 2144.06). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). In addition, as evidenced by Unger et al., a person of ordinary skill in the art would have recognized the suitability of utilizing an elastomeric valve system for the intended purpose of facilitating fluid control within a microfluidic device (see MPEP § 2144.07).

Furthermore, the Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of utilizing the elastomeric microfluidic valve system, as taught by Unger et al., with the microfluidic apparatus of Knapp et al., for permitting the controlled movement and mixing of fluids within the microfluidic apparatus. Therefore, it would have been obvious to a person of ordinary skill in the art to utilize the elastomeric microfluidic valve system, as taught by Unger et al., with the microfluidic apparatus of Knapp et al., for permitting the controlled movement and mixing of fluids within the microfluidic apparatus.

Regarding claim 4, Unger et al. teach that the disclosed elastomeric valve system may comprise a pair of valve systems (e.g., 25A, 32A & 32B), which is capable of forming a holding space between the valve systems when actuated in which a fluid can be retained (see col. 24, lines 23 – 43; figure 24B). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). Furthermore, the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114).



Regarding claims 5, 6 and 29, Unger et al. teach that the disclosed elastomeric microstructures may be utilized as either a pump or valve mechanism (see col. 7, lines 45 – 64).

Regarding claims 9 and 12, Unger et al. teach that the fluid pump system comprising the elastomeric microfluidic system may comprise a plurality of elastomeric valve systems (e.g., 25A, 32A, 32B & 32C) (see figure 24B).

Regarding claims 10 and 11, Unger et al. teach that a control channel (30) of the fluid pump mechanism comprises at least one closed valve system or constricted region (e.g., 25A & 32A) (see figure 24B).

Regarding claim 13, as discussed above, Unger et al. teach the recited structure of the fluid pump system and the functional capability (i.e., fluid pumping rate of about 2.5 nl/s or less) of the fluid pump mechanism, as shown in figure 25. Regarding claims drawn to a product or apparatus statutory class of invention, when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent. The Courts have held that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. See *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) (see MPEP § 2112.01, see also MPEP § 2112). Therefore, it is inherently anticipated that the fluid pump mechanism disclosed by Unger et al. is capable of providing a relatively constant flow rate of about 0.02 μ l/min or less.

Regarding claim 14, Unger et al. teach that the valve system may be actuated by a pneumatic means (see col. 20, lines 23 – 27).

Regarding claim 15, Unger et al. teach the incorporation of integrated intersecting first (30) and second (32) microfluidic channels, wherein the first (30) microfluidic channel would be in fluid communication with the port (e.g., 1370 & 1445) of the microfluidic apparatus of Knapp et al. (see col. 24, lines 9 – 22; figure 23A).

Regarding claim 26, Unger et al. teach the incorporation of a vacuum pump mechanism (see col. 34, lines 61 – 66).

Regarding claim 27, Unger et al. teach the incorporation of a pressurization means (see col. 19, lines 22 – 53).

Regarding claim 28, Unger et al. teach the incorporation of a microfluidic channel comprising a narrow section (see col. 25, lines 23 – 29).

Regarding claim 33, Unger et al. teach the incorporation of a plurality of fluid channels (30A & 30B) within the system (see col. 26, lines 44 – 53; figure 30)

Regarding claims 34 and 35, Knapp et al. teach that the fluid inlet or port structure further comprises an elongated capillary, capillary element or electropipettor protruberance (e.g., 1405) having a capillary channel disposed therethrough, wherein the capillary channel is in fluid communication with the microfluidic channel (see col. 5, lines 7 – 36; col. 10, lines 16 – 21; col. 56, lines 6 – 37; figure 14).

Regarding claims 36 – 45, as discussed above, Knapp et al. in view of Unger et al. teach all of the structure of the claimed method, which merely recites the conventional operation of that structure. Regarding process or method claims, a prior art device anticipates a claimed process, if the device carries out the process during normal operation (see MPEP § 2112.02). The Courts have held that when a prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed that the device will inherently perform the claimed process. See *In re King*, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986). Therefore, it would have been obvious to a person of ordinary skill in the art to perform the method recited in the instant claims upon the system taught and suggested by Knapp et al. in view of Unger et al.

Regarding claims 46 – 60, Unger et al. teach that the disclosed device and methods are ideally suited for controlling and channeling fluid movement with microfluidic devices (see col. 1, line 64 – col. 2, line 2). As discussed above, Knapp et al. in view of Unger et al. teach all of the structure of the claimed method, which merely

recites the conventional operation of that structure. Regarding process or method claims, a prior art device anticipates a claimed process, if the device carries out the process during normal operation (see MPEP § 2112.02). The Courts have held that when a prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed that the device will inherently perform the claimed process. See *In re King*, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986). Furthermore, Knapp et al. do disclose. Therefore, it would have been obvious to a person of ordinary skill in the art to perform the method recited in the instant claims upon the system taught and suggested by Knapp et al. in view of Unger et al.

2. Claims 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knapp et al.

Regarding claim 17, Knapp et al. neither specifically teach nor suggest a plurality of ports and capillary or electropipettor protruberances for the disclosed microfluidic apparatus. However, the Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a plurality of ports and capillary or electropipettor protruberances for the disclosed microfluidic apparatus.

Regarding claim 20, Knapp et al. neither teach nor fairly suggest a body structure further comprising a plurality of ports and a plurality of capillary elements, wherein each of the ports have a capillary element inserted therethrough. However, the Courts have held that the mere duplication of parts, without any new or unexpected results, is within

the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a body structure further comprising a plurality of ports and a plurality of capillary elements, wherein each of the ports have a capillary element inserted therethrough for the disclosed microfluidic apparatus.

Allowable Subject Matter

Claims 8 and 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 8 and 32, the cited prior art neither teach nor fairly suggest the further incorporation of a capacitor within the fluid pump control channel, wherein the capacitor is capable of delaying the actuation of the control channel.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Wenzel et al. teach a micropump. Parce et al. teach controlled fluid transport in microfluidic devices. Soane et al. teach methods for fabricating enclosed microchannel structures.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571)

272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

